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PATENT

Attorney Docket No. 6270-701.201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Sarah S. Bacus et al.	)	
	)	
Application No.: 10/735,118	)	Art Unit: 1642
	)	
Filed: December 11, 2003	)	Examiner: Unassigned
	)	
Title Method For Predicting The Response to	)	
HER2-Directed Therapy	)	

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:

(1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --

(2) It is being filed within 3 months of entry of a national stage  
-- OR --

(3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --

(4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

a certification as specified in §1.97(e) is provided below; **or**

a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

A. a certification as specified in §1.97(e) is completed below; **and**

B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**

C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:

In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.

If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

There are no listed references which are not in the English language.

The relevance of those listed references which are not in the English language is as follows:

Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).

Attached are the following non-published pending patent applications which may be deemed relevant.

*Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 6270-701.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By: 

Shirley Chen, Ph.D. Ph.D.  
Reg. No. 44,608

Dated: January 6, 2005

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## **CERTIFICATION**

*(Attachment to Information Disclosure Statement)*

37 *C.F.R. §1.97(e)(1).* **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

37 *C.F.R. §1.97(e)(2).* **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Respectfully submitted,

By:



Shirley Chen, Ph.D.  
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Dated: January 6, 2005

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Substitute for form 1449/PTO  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
*(Use as many sheets as necessary)*

<p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.</p> <p>U.S. PATENT AND TRADEMARK OFFICE</p> <p><b>Substitute for form 1449/PTO</b></p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	10/735,118
				Filing Date	December 11, 2003
				First Named Inventor	Sarah s. Bacus
				Art Unit	1642
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	6270-701.201

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> – Number <sup>3</sup> – Kind Code <sup>3</sup> (if known)				
		EP 0 656367 A1	06/07/1995	Becton Dickinson and Company	1-83	

Examiner Signature		Date Considered	
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**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3.). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<p>Substitute for form 1449/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
				Application Number	10/735,118
				Filing Date	December 11, 2003
				First Named Inventor	Sarah S. Bacus
				Art Unit	1634
				Examiner Name	Unassigned
Sheet	2	of	2	Attorney Docket Number	6270-701.201

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
		BACUS, S.S., et al., "HER2/Neu Oncogene Expression and Proliferation in Breast Cancers," <i>American Journal of Pathology</i> , (1990), VOL. 137, No. 1, pages 103-111, XP-000998483.			
		GUILLERNARD, V., et al., "Selective Delivery of Chemotherapeutics to Cancer Cells Via Growth Factor Receptors: Towards the Development of Smart Chemotherapeutic Agents, <i>Proceedings of the Annual Meeting of the American Association for Cancer Research</i> , (2002), page 76, XP-001180581.			
		BACUS, S. et al, "Differences in Reponse of Breast Cancer Molecular Profiles of Patients likely to Respond Either to erbB Tyrosine Kinase Inhibitors or to erbB Targeted Antibodies," <i>Breast Cancer Research and Treatment</i> (2003), Vol. 82, No. suppl. 1, pages S-72-S-73, XP009034953.			
		LEITZEL, K., et al., "Increased Serum IGF Receiptor (IGF-IR) in Patients With Elevated Serum HER-2/neu," <i>Breast Cancer Research and Treatment</i> (2003), Vol. 82, No. suppl. 1, pages S-94, XP009034954.			
Examiner signature				Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.